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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/026,578	12/17/2001	Thomas Schmidt	VJP-1030-US	1170

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EXAMINER
ROBINSON, HOPE A

ART UNIT	PAPER NUMBER
1652	

NOTIFICATION DATE	DELIVERY MODE
08/10/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DOCKETING@BIOTECHNOLOGYLAWGROUP.COM

Office Action Summary	Application No.	Applicant(s)	
	10/026,578	SCHMIDT, THOMAS	
	Examiner	Art Unit	
	HOPE A. ROBINSON	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *5/22/09*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34,36,37,41-45 and 47-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16,17,32-34,36,37,41-45 and 47-51* is/are rejected.

7)☒ Claim(s) *32-34,41-45 and 47* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 January 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/22/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Application Status

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 22, 2009 has been entered.

Claim Disposition

2. Claims 1-34, 36-37, 41-45 and 47-51 are pending. Claims 16-17, 32-34, 36-37, 41-45 and 47-51 are under examination.

Information Disclosure Statement

3. The Information Disclosure Statement filed on May 22, 2009 has been received and entered. The references cited on the PTO-1449 Form have been considered by the examiner and a copy is attached to the instant Office action.

Claim Rejections - 35 USC 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 16, 37 and 49-51 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention is directed to a fusion protein comprising a streptavidin-binding peptide linked to any protein (see for example claim 16) wherein the streptavidin binding peptide binds to at least one streptavidin and a streptavidin mutein and wherein the streptavidin binding peptide comprises a sequential arrangement of two modules described as each having -His-Pro-Baa (Baa being glutamine, asparagine an methionine) and at least one module being -His-Pro-Gln-Phe (SEQ ID NO:6). The claimed invention is also directed to each module having between zero and 50 amino acids between the two modules and the two modules forming parts of 3 modules, 4 modules or 5 modules. Additionally the claimed invention is directed to said streptavidin mutein for example fused to any full-length protein, any protein fragment or any protein mutant. The claimed invention is highly variable and encompasses a large variable genus of proteins not adequately described. A skilled artisan cannot envision the detailed chemical structure of the fusion protein as claimed absent adequate written description.

The claims provide for example SEQ ID NO:3, 6, 7, 8, 9 and 11, however, only SEQ ID NO:3 and 11 represents a structure bearing two modules and there is no indication of what a structure with a mutein having 5 modules looks like. A representative number of species needs to be provided based on the large variable genus encompassed in the claims. The specification fails to provide any additional representative species of the claimed genus to show that applicant was in possession of the claimed genus. A representative number of species means that the species which are adequately described are representative of the entire genus. The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, disclosure of drawings, or by disclosure of relevant identifying characteristics, for example, structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus.

Further, *Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir.1991)*, states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in *possession of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*" (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (See *Vas-Cath* at page 1116). The skilled artisan cannot envision the detailed chemical structure

of the encompassed genus of polypeptides, and therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. *See Fiers v. Revel, 25 USPQ2d 1601 at 1606 (CAFC 1993).*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

5. Claim 36 is rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter, which applicant (s) regard as their invention.

Claim 36 lacks clear antecedent basis since claim 16 recites that each module comprises “His-Pro-Baa", wherein Baa is selected from glutamine, asparagine and methionine” and wherein at least one module is His-Pro-Gln-Phe (SEQ ID NO:6). Note that claim 34 indicates that each module has to be His-Pro-Gln.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

6. Claims 16-17 and 48 are rejected under 35 U.S.C. 102(e) as being anticipated by Ley et al. U.S. Patent No. 6,906,176, June 19, 2000).

Ley et al. teach a fusion protein comprising streptavidin binding domain such as His-Pro-Gln-Phe (SEQ ID NO:6, see column 6 of the patent). The patent discloses that the streptavidin binding domain can have several modifications such as additional sequences added in tandem and provides for example SEQ ID NOS:5, 7, 210 and 211 which falls within the scope of the invention (see column 6 of the patent). In addition, the patent discloses that the streptavidin binding domain can be fused at the amino terminal end of the protein of interest.

Therefore the limitations of the claims are met by the reference.

Response to Arguments

7. The response filed has been received and entered. The Declaration of Dr. Thomas Schmidt has been considered in full. Note that the 112 first paragraph written description rejection remains and has been amended based on the Declaration provided. In addition, a new ground of rejection has been instituted under 35 USC 102(e) based on the arguments presented in the Declaration. Essentially the issue that remains in the 112, first paragraph written description pertains to the streptavidin mutein, the enormous variability given of zero to 50 amino acids between the modules and the language of the two modules forming part of 3, 4 or 5 modules. It is suggested that claims 49-51 are cancelled or exemplified a structure and that the language of "mutein" and "mutant" are deleted from the claims. In addition, the claims provide SEQ ID NO:3 and 11 which exemplifies the two modules, however, the structures do not extend to 40 or 50 amino acids in length, instead fall within the disclosed range of "preferably at least 8 and up to preferably not more than 30" amino acids (see paragraph [0036] of the PGPUB20030083474 version of the instant application). The specification disclose that, "streptavidin muteins are polypeptides which are distinguished from the sequence of wild-type streptavidin by one or more amino acid substitutions, deletions or additions and which retain the binding properties of wt-streptavidin. Streptavidin-like polypeptides and streptavidin muteins are polypeptides which essentially are immunologically equivalent to wild-type streptavidin and are in particular capable of binding biotin, biotin derivative or biotin analogues with the same

or different affinity as wt-streptavidin. Streptavidin-like polypeptides or streptavidin muteins may contain amino acids which are not part of wild-type streptavidin or they may include only a part of wild-type streptavidin. Streptavidin-like polypeptides are also polypeptides which are not identical to wild-type streptavidin, since the host does not have the enzymes which are required in order to transform the host-produced polypeptide into the structure of wild-type streptavidin." (see paragraph [0027]. In addition, the instant specification discloses that " particular preference is given to streptavidin muteins having the sequence Ile-Gly-Ala-Arg or Val-Thr-Ala-Arg " and references the patent 6103493 (see paragraph [0046]), however, the claims are not limited to such.

Applicant states that the binding characteristics of the fusion protein to streptavidin are determined by the structure of the streptavidin binding tag (affinity tag) not by the polypeptide sequence of interest to which the affinity tag is linked. This argument is not persuasive based on the above description provided for the tag. The tag could have several modules which are not adequately described (see claims 16, 37 and 49-51). The protein partner is important since binding might not occur depending on the fragment or variant thereof (see for example the variability contemplated in claim 17). The claims encompass any streptavidin mutein and any protein and its fragments or variants; absent any correlation between function and structure. Thus the rejection remains.

With regard to the art rejection, note that the rejection of record is withdrawn, thus applicant's comments are moot. Note, however, that a new rejection has been instituted for the reasons set forth above.

Conclusion

8. No claims are presently allowable. Claims 32-34, 41-45 and 47 are objected to as depending from a rejected based claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday.
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached at (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Hope A. Robinson/

Primary Examiner, Art Unit 1652